EXHIBIT B

CLINICAL STUDY

Prevalence and Clinical Consequences of Fracture and Fragment Migration of the Bard G2 Filter: Imaging and Clinical Follow-up in 684 Implantations

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ABSTRACT

Purpose: To investigate the prevalence and clinical sequelae of G2 filter (Bard Peripheral Vascular, Tempe, Arizona) fractures and fragment migration.

Materials and Methods: Patients who underwent G2 filter placement between October 2005 and February 2010 were assessed for filter fractures and complications. Fracture prevalence was estimated at various time points based on data from patients with known fracture status.

Results: Among 829 patients who underwent G2 filter placement, 684 had follow-up imaging and qualified for the study (381 men and 303 women; average age, 60.3 y; range, 15.8–95.2 y). For 541 (79%) patients, at least one image was available that contained the filter (imaging follow-up interval, 14.9 mo ± 20.0; range, 0–78.6 mo); images that did not include the filter but may have shown the migrated fracture fragment were available for 143 (21%) patients (follow-up interval, 11.2 mo ± 19.3; range, 0–83.4 mo). There were 16 fractured limbs identified in 13 patients (incidence, 1.9%; follow-up interval, 30.4 mo ± 18.7; range, 5.5–76.5 mo). Fracture fragments were identified in the pulmonary arteries (n = 4), right ventricle (n = 2), pericardium (n = 1), iliac vein (n = 1), and kidney (n = 1). Four fracture limbs remained near the filter; the remaining three could not be located. All patients with filter fracture were asymptomatic. The estimated 5-year fracture prevalence was 38% (95% confidence interval, 22.9%, 54.8%).

Conclusions: The early occurrence of G2 filter fractures was low, but the incidence increased over time. No life-threatening events occurred in patients with filter fracture during the study time frame.

ABBREVIATION

IVC = inferior vena cava

An inferior vena cava (IVC) filter fractures when structural failure and separation of the components of the filter occur. These fractures can have serious consequences; migration of the fractured components has been known to cause life-threatening complications such as arrhythmia and pericardial tamponade (1–4). The reported incidence of fracture in retrievable filters ranges from 0–25%, with wide variations among filter models and length of follow-up (1,5–7). The earlier models of Bard filters Recovery and G2 (Bard Peripheral Vascular, Tempe, Arizona) have the highest reported fracture incidence (8,9). Many of the reported fractures in the Manufacturer and User Facility Device Experience database are associated with the G2 filter (157 of 500; 31%) (8).

The G2 filter, a redesign of the Recovery retrievable filter, was approved by the U.S. Food and Drug Administration for permanent use in 2005 and for retrievable use in 2008 (10). Although the G2 filter was replaced in 2009 with a new model, many patients still have the G2 filter in situ for permanent indications. The

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prevalence of G2 fractures and the severity of associated complications in such patients are largely unknown because of limited data. The goal of this retrospective study was to assess the prevalence of filter fracture and its clinical sequelae in a cohort of patients who underwent G2 filter placement at our institution.

MATERIALS AND METHODS

This study was approved by our institutional review board. A retrospective review of the departmental inventory database was performed to identify consecutive G2 filter placements done between October 2005 and February 2010 at a single tertiary-care center. Patients included in this study had at least one imaging study that was performed after filter placement, which was used to determine the presence of filter fracture directly or indirectly. Demographic and clinical data were retrieved from our main hospital's electronic medical records (Epic Systems, Verona, Wisconsin), and mortality data were obtained from the Social Security Death Index. All images were retrieved from the image archiving database (AGFA, Mortsel, Belgium) in our health care system (including the main hospital complex and affiliated hospitals at which many patients received care after filter placement). Imaging studies included cavograms performed at filter retrieval and plain radiographs and computed tomography (CT) scans of the chest, abdomen, pelvis, and lumbar spine.

Two fellowship-trained interventional radiologists independently reviewed the images to identify cases of fracture and migration of filter fragment from the original filter position. The imaging studies were divided into "direct" and "indirect" categories (11). Direct imaging studies contain the filter and include any abdominal CT scans or plain radiographs of the abdomen; kidneys, ureter, and bladder; and lumbar spine. Indirect studies do not contain the filter itself but may visualize a fracture fragment that has migrated to the lung, heart, or pelvis. These studies include chest CT scans and plain radiographs of the chest and pelvis. If no fracture was found on the most recent direct image, the study was labeled negative for fracture. The time interval from placement was calculated and used to determine the maximum fracture-free period. If a fracture or fragment migration was identified, all previous images were examined to identify the first positive study (ie, earliest evidence of fracture or migration). Information about fracture-related complications (if present) was obtained from review of inpatient and outpatient notes within the electronic medical record.

The prevalence of filter fracture at various time points after placement was estimated based on data from patients whose fracture status was known at that time. Agresti-Coull 95% confidence intervals, which give an approximate confidence interval for a binomial proportion, were also calculated for fracture prevalence (12). When there were no known fractures at a certain time point, a simple method for calculating the upper confidence bound for a binomial proportion when no events are observed was used (13). The basic idea was to identify the largest value of a population proportion (p) for which the probability of observing our results (0/N) was at least α, where α is the significance level for the interval. The upper confidence bound then was found by solving $(1 - p)^N = \alpha$ for p.

RESULTS

From October 2005 to February 2010, 829 consecutive patients underwent G2 filter placement at our institution. For 684 patients, at least one image was available that could be used for evaluation of fracture or migration after filter placement; the remaining 145 patients without follow-up imaging were excluded from the analysis. Of the 684 patients, 381 were male and 303 were female, with an average age of 60.3 years (range, 15.8–95.2 y) at the time of filter placement. The mean clinical follow-up period for study patients was 22.7 months ± 24.5 (range, 0–83.4 mo).

The imaging modalities and times to follow-up among study patients are shown in Table 1. The mean imaging follow-up interval for all study patients was 14.1 months ± 19.9 (range, 0–83.4 mo). For 541 (79%) of 684 patients, at least one direct follow-up image was available, with a mean follow-up interval of 14.9 months ± 20.0 (range, 0–78.6 mo); for 143 (21%) patients, only indirect follow-up images were available, with a mean follow-up interval of 11.2 months ± 19.3 (range, 0–83.4 mo) (Table 2). For patients with direct imaging available, 177 patients (32.7%) had a follow-up period > 1 year; for patients with indirect imaging available, 33 (23.1%) had a follow-up period > 1 year.

There were 146 (21.3%) patients who presented for filter retrieval, and 133 of these patients (91.1%) had

Table 1. Summary of Follow-up Imaging in 684 Patients

Type of Imaging	Studies (No.)*	Follow-up Interval (mo)†
Cavogram	146	4.85 (0.11–51.52)
Chest radiograph	368	15.53 (0–83.38)
Chest CT	41	15.85 (0.01–68.92)
Abdominal radiograph	235	14.52 (0–77.71)
Kidney, ureter, and bladder radiograph	9	17.1 (0.11–77.29)
Lumbar spine radiograph	12	32.05 (5.09–57.37)
Pelvic radiograph	24	20.27 (0.57–75.26)
Abdominal CT	261	12.76 (0–75.53)
Total	1,096	—

CT = computed tomography.
*Regardless of the number of images available for a single patient, any same image modality was counted only once.
†Mean value (range).

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Table 2. Imaging and Clinical Follow-up in 684 Patients

Patient Groups	Imaging Follow-up (mo)*	Clinical Follow-up (mo)*
Patients with direct image available (n = 541)	14.9 ± 20.0 (0–78.6)	25.2 ± 24.8 (0–80.1)
Patients with indirect image available (n = 143)	11.2 ± 19.3 (0–83.4)	12.7 ± 20.1 (0–83.4)
Deceased patients (n = 291)	6.2 ± 10.5 (0–59.5)	7.1 ± 10.8 (0–59.5)
Alive patients (n = 393)	20.0 ± 22.9 (0–83.4)	32.0 ± 25.6 (0–83.4)

*Mean value ± SD (range).

their filters successfully removed (mean time to removal, 4.9 mo ± 5.5; range, 0.1–51.5 mo). There were 291 patients who died of causes unrelated to the filter, with a mean imaging follow-up interval of 6.2 months ± 10.5 (range, 0–59.5 mo); 282 of these patients (96.9%) died with their filters in place (4 having undergone unsuccessful retrievals), and 9 of these patients (3.1%) died after filter removal (mean interval from filter placement, 18.8 ± 16.1 mo; range, 0.8–54.9 mo). At last follow-up, 393 patients were alive with a mean imaging follow-up interval of 20.0 months ± 22.9 (range, 0–83.4 mo). Of these 393 patients, 269 had filters in situ (9 patients having undergone unsuccessful retrievals), and 124 had undergone successful filter retrieval. Among patients alive at last follow-up, 325 had direct imaging follow-up with a mean follow-up interval of 19.9 months ± 22.8 (range, 0–78.6 mo), and 68 had only indirect imaging follow-up with a mean follow-up interval of 20.5 months ± 24.0 (range, 0–83.4 mo).

In 13 of 684 patients (1.9%), 16 fractured limbs (11 arms and 5 legs) were identified. The average interval from placement to identification of fracture was 30.4 months ± 18.7 (range, 5.5–76.5 mo). Limb fracture was identified in two patients at filter retrieval. In one patient, a fractured arm was identified at the right kidney, and no fragment retrieval was attempted. In the second patient, the limb fracture occurred during retrieval. The fractured limb migrated to the distal IVC and was subsequently removed. All patients with limb fracture had at least one direct image of the filter except for one patient, in whom the single short limb was identified within the left lung on a chest radiograph (Fig 1). Of the 16 fractured limbs, 9 had distant migration, including 4 to the pulmonary arteries, 2 to the cardiac chambers (Fig 2a, b), and 1 to each of the following sites: pericardium (Fig 3a, b), iliac vein (Fig 4), and kidney (Fig 5). Four fractured limbs remained near the filter, and the remaining three fragments could not be visualized on the available studies. Of the 13 patients with limb fractures, 2 died of underlying medical conditions, and 11 were asymptomatic at the last clinical visit (Table 3). There was no documentation of chest pain, arrhythmia, or other symptoms possibly related to migration of fracture fragments among the 13 patients with fractured limbs during an average interval of 9.2 months ± 13.6 from the first identification of filter fracture to the last follow-up date.

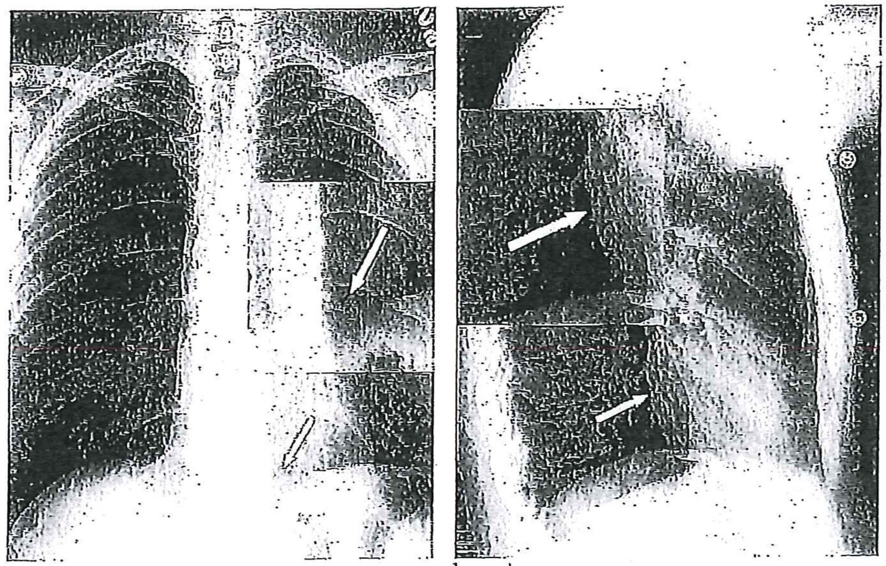
Figure 1. Posteroanterior chest radiograph demonstrates a fractured long limb (arrow) that embolized to the left pulmonary artery. There were no direct images for this patient that visualized the filter proper.

Point and interval estimates of fracture prevalence are shown in Table 4. For the first year after filter placement, estimates of fracture prevalence were low: 0.9% at 90 days, 2.7% at 180 days, and 3.8% at 360 days. These estimates continued to increase over time, with the estimated fracture prevalence reaching 38% at 5 years after filter placement (95% confidence interval, 22.9%, 54.8%).

DISCUSSION

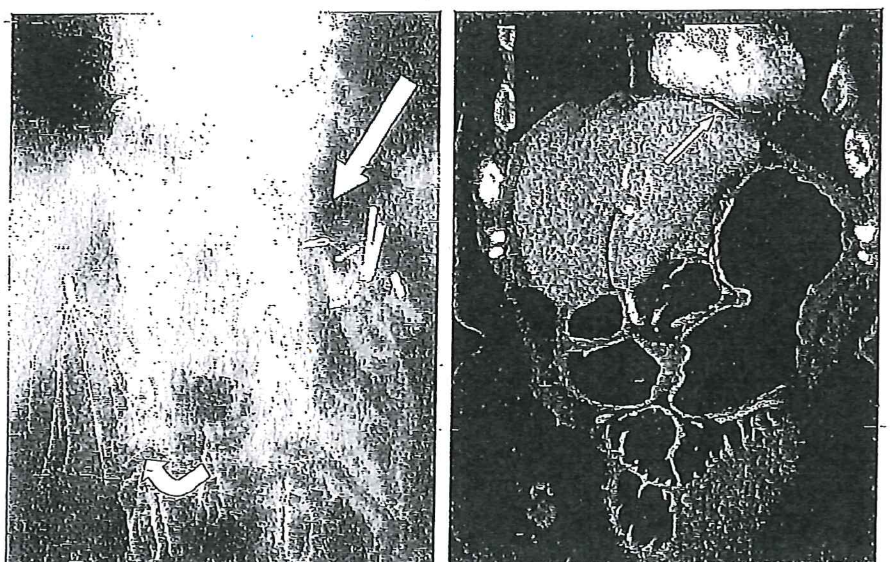
The incidence of G2 filter fractures was low in the present study, but the estimated risk of fracture increased with longer filter indwelling time. No life-threatening events occurred in patients with filter fractures during the follow-up interval.

The construction of the G2 filter was modified from the original design of the Recovery filter and included thicker leg hooks, a wider leg span, and longer arms with a more



a. b.

Figure 2. Posteroanterior (a) and lateral (b) chest radiographs demonstrate an embolized short limb (arrows) projecting over the right ventricle. Insets show a magnified view of the fracture fragment.



a. b.

Figure 3. Posteroanterior abdominal radiograph (a) and coronal view of volume-rendered CT image (b) demonstrate a fractured short limb (arrows) that migrated to the pericardial space. In addition, there is a fractured long limb (curved arrow) inferior and medial to the main body of the filter (a).

progressive angle of the arm wires at the filter apex and inwardly-curved ends. These modifications were aimed at reducing the occurrence of filter migration, fracture, and tilting without compromising the retrievability of the filter (14). Studies have reported a lower incidence of fracture with the G2 filter than with the Recovery filter. Nicholson et al (1) reported a 12% fracture rate with the G2 filter over 23.5 months ± 8.3 among 52 patients and a 25% fracture rate with the Recovery filter over 50.2 months ± 4.9 among 28 patients. Vijay et al (15) found that G2 filters were significantly less likely to fracture than Recovery filters over 36 months of follow-up, a difference the authors attributed to the change in filter design. Table 5 summarizes the overall incidence of G2 filter fractures as reported in previous studies (1,2,9,14–27). Variations in reported fracture rates may be caused in part by differences in sample size or filter indwelling time or both.

In the present study, the earliest G2 fracture was identified at 5.5 months, and the risk of fracture

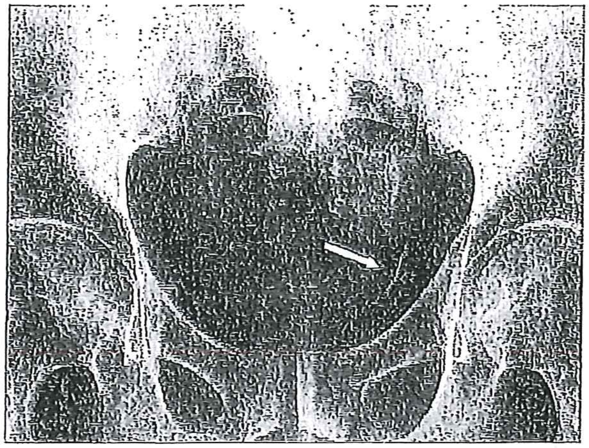


Figure 4. Plain radiograph of the abdomen demonstrates a fractured long limb (arrow) that embolized to the left iliac vein.

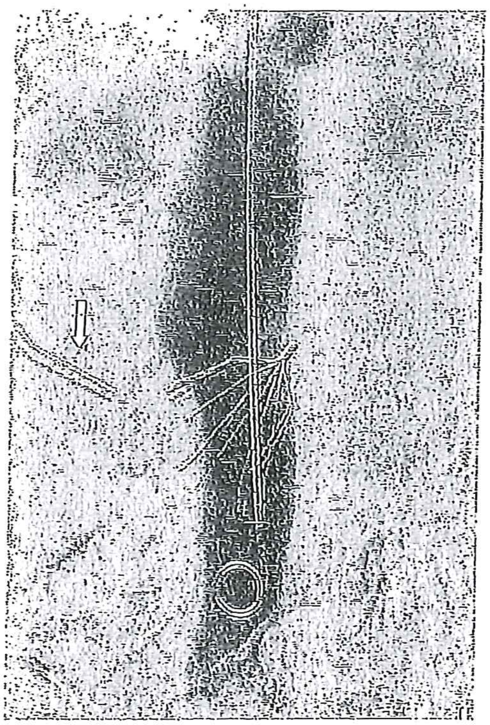


Figure 5. IVC carbon dioxide-cavogram shows a fractured long limb that migrated to the right renal vein (arrow). The filter itself is tilted and deformed.

increased over time, reaching 38% at 5 years after filter placement. This estimate of fracture prevalence is similar to the predicted rate previously reported for Recovery filters (40% at 5.5 y in 363 patients) (6). In other studies, G2 filter fracture usually occurred > 180 days after filter implantation (2,28). These results suggest that indwelling time is an important factor in determining the risk of fracture in patients with a G2 filter.

The most serious complication associated with filter fracture is cephalad migration of the fracture fragment to the heart, risking fatal arrhythmia, laceration of the cardiac wall, and cardiac tamponade (1,3,4,29). The occurrence of cephalad migration varies among the reports. Nicholson et al (1) reported that 64% (16 of 25) of fracture fragments of 13 Bard filters (7 Recovery and 6 G2 filters) migrated to the heart (n = 10) and lungs (n = 6). In a previous study of Recovery filters, 35% (9 of 26) of filters exhibited cephalad migration (6). Although no cases of life-threatening events attributable to G2 filter fractures have been reported to date, the risk of ventricular tachycardia, cardiac tamponade, hemopericardium, and sudden death from cephalad or cardiac migration of the filter fragment (as seen in the Recovery and G2X filters) is still present (1,2,15). In the present study, 54% (7 of 13) of fracture components migrated in the cephalad direction, with embolization of four fragments to the lung, two to the cardiac chambers, and one into the pericardium. It is unclear how a fracture fragment can migrate to the pericardium. The present study and previous reports by Hull et al (30) and Tam et al (6) found that a fragment in the right ventricle does not always result in symptoms.

Caring for patients with G2 filters in situ presents a clinical dilemma. The Food and Drug Administration approved all retrievable filters for permanent and retrievable indications. Retrievable filters were favored over permanent filters because they offered greater flexibility in case management; additionally, the literature has not offered data supporting the superiority of permanent filters over retrievable filters in patients requiring long-term deep vein thrombosis protection. In our practice, retrievable G2 filters were used for both permanent and temporary indications, but approximately 80% of patients received filters for permanent indications. A low percentage of this patient cohort returned for filter retrieval despite the current consensus dictating prompt removal of the filter when deep vein thrombosis protection is no longer needed. Several factors led to this low retrieval rate, including a high number of patient deaths shortly after filter insertion, a large number of international and out-of-state patients, and a lack of surveillance program at the time.

In patients with a permanent indication for deep vein thrombosis protection, replacing an intact G2 filter with another device with unknown long-term risks is difficult to advocate. Active long-term surveillance may find more silent fractures but may also needlessly increase patient anxiety. Cases of known filter fractures present even greater challenges. Studies have demonstrated the feasibility and benefit of removing a fractured IVC filter and accessible filter fragments (2,9). However, a decision to retrieve such a fragment ultimately depends on the operator, who must balance the risks and benefits of the procedure. In this study, all fractures and fragment migrations were incidentally identified and clinically asymptomatic. In addition, most of the fracture

Table 3. Fracture and Migration in 13 Patients

	Fracture			Follow-up Interval (mo)		
Sex/Age (y)	Arm	Leg	Migration Site	First Positive*	Last Normal†	Last Visit‡
M/45	1		Right ventricle	24	0.3	24
M/54		1	Left iliac vein	38.7	NA	38.7
F/82		1	Right renal vein	5.5	NA	18.5§‖
F/69	2		Right ventricle, at filter	49.5	35.3	49.5
F/49	1		Left pulmonary	22.6	16.5	51.9
F/66	1		Unknown	76.5	11.4	76.5
F/74	1		Pericardial	34.9	NA	40.7
M/71	1		At filter	32.6	NA	56§
F/19	1		Left pulmonary	12.2	NA	19.2‖
M/56	2	1	1 right pulmonary, 2 unknown	23	8	63.9
F/32		1	At filter	22.5	19.7	51.5§
F/66		1	At filter	12.2	NA	12.5§
F/83	1		Right ventricle	41.2	21.8	41.9

F = female; M = male; NA = not available.
*Interval between filter placement and first imaging study to identify filter fracture.
†Interval from filter placement to the date of last imaging study on which filter was seen to be normal.
‡Interval from filter placement to the last date of clinical follow-up.
§Filter was removed.
‖Patient died.

Table 4. Estimate of G2 Filter Fracture Prevalence Over Time

Time Point after Filter Placement	Patients without Known Fracture (n)	Patients with Known Fracture (n)	Fracture Prevalence	
			Estimate (%)	95% CI (%)
3 mo	337	0	0	0.000, 0.009
6 mo	225	1	0.44	0.000, 0.027
1 y	158	1	0.63	0.000, 0.038
2 y	102	6	5.6	0.023, 0.118
3 y	75	9	10.7	0.055, 0.193
4 y	42	11	20.8	0.118, 0.336
5 y	20	12	37.5	0.229, 0.548

CI = confidence interval.

fragments were situated in locations that would make retrieval difficult, impossible, or highly risky, such as within a distal pulmonary artery branch or within the pericardium. We are unsure whether all patients with G2 filters should be routinely monitored for possible filter retrieval and whether migrated fracture fragments should always be retrieved. However, we advocate removal of any symptomatic fracture fragment or fragment with embolization to a high-risk location if possible.

This study had several limitations. This was a retrospective review of imaging studies performed in patients who returned to our institution for ongoing medical issues. There is no standard imaging follow-up protocol for patients with G2 filters. Not all patients in this study had imaging of the filter; 21% of patients had indirect images only. The average follow-up time was 14.1 months for all available imaging studies, with filters being retrieved in a large number of patients in the first year and additional loss of patients to death or lack of follow-up. Finally, the clinical information, including cause of death, was based on retrospective electronic medical records review without autopsy, imaging studies, or clinical or telephone follow-up focusing on filter-related complications.

In conclusion, this series demonstrated a low overall initial rate of filter fractures in patients with G2 filters, but the estimated fracture risk progressively increased with longer filter dwell times. No life-threatening events related to fracture of the G2 filter were observed over a limited period of time. Patients no longer requiring a filter should be scheduled for retrieval because of the risk of filter fracture and migration, but the benefit of screening patients with a G2 filter in situ for possible replacement of the filter is less clear.

Table 5. Fractures and Related Complications in G2 Filter Studies

Study	Filters (No.)	Fractures (No.)	Dwell Time*	Fracture Fragments (No.)	Migration (No.)	Fracture-Related Symptoms	Fragment Retrieval
Nicholson et al (1)	52	6	24.6 mo (10–35 mo)†	8	6 IVC, 1 lung, 1 liver	No	No
Kuo et al (2)‡	9	9§	1,276 d (351–2,263 d)†	Unknown		No	NA
Dinglasan et al (9)‡	8‖	8	13.5 mo (4–61 mo)	10	5 IVC, 2 extraluminal, 2 IVC wall, 1 lung	Not reported	6 (60%)
Oliva et al (14)	51	0	53.4 d (7–242 d)	0	NA	NA	NA
Vijay et al (15)‡	350	19	692 d (65–1,771 d)	41¶	10/77¶	Not reported	15/77¶
Charles et al (16)	26	0	122 d (11–260 d)	0	NA	NA	NA
Binkert et al (17)	85	1	92 d†	2	Out of the cava	No	No
Kim et al (18)	10	0	24.7 mo		NA	NA	NA
Uberoi et al (19)	95	0	77 d (34–154 d)		NA	NA	NA
Nazzal et al (20)	1	0	1 d		NA	NA	NA
Malek et al (21)	3	0	285 d (20–2,091 d)		NA	NA	NA
Janvier et al (22)	1	0	18 mo		NA	NA	NA
Hermsen et al (23)	16	0	228 d (33–441 d)		NA	NA	NA
Gupta et al (24)	1	1	1–2 y	2	1 right lung, 1 left upper abdomen	No	No
Damascelli et al (25)	107	1	5 mo	1	1 left lung	No	No
Caceres et al (26)	1	0	3 y		NA	NA	NA
Bui et al (27)	1	0	4 mo		NA	NA	NA
Total	817	45 (5.5%)		74			

IVC = inferior vena cava; NA = not applicable.
*The time from G2 filter placement to available image for all filters in a particular study (range). G2 filters without images after placement were excluded.
†Represents the true fracture interval (time from G2 filter placement to time fracture was reported).
‡The authors' group published several other G2 filter–related studies, which were excluded from this table because of data overlapping.
§The number of G2 fractures could not be calculated because the article did not specify which fractures involved G2 filters (fractures were reported in 31 of 47 conical-shaped filters). There was the potential for fracture in up to 9 G2 filters.
¶This study included 548 patients, 63 fractures, and 77 fractured limbs for three types of Bard filters (Recovery, G2, and G2X). Specific data regarding G2 filters could not be retrieved from the article.
‖There were 148 IVC filters studied, including Bard Recovery, G2, and Celect filters. No details were provided about the total number of each filter type.

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